REMARKS

Applicants respectfully request entry of amendments to claims 1-4, 6-10, and 12-14, and new claim 40. Please cancel claims 5 and 11, and withdraw claims 15-39, without prejudice or disclaimer. Support for the amendments can be found throughout the specification, including paragraphs [0006], [0014], [0043], [0045], Table 3, the Sequence Listing, and the originally filed claims and, therefore, do not add new matter.

Applicants submit that pending claims 1-4, 6-10, 12-14, and 40 are in condition for allowance, and respectfully request that the claims as amended be entered.

Restriction Requirement

Applicants wish to thank the Examiner for rejoining the primer pairs and acknowledging Applicants' request for rejoinder of process claims with an allowable product as required by M.P.E.P. §806.05(h).

Rejection Under 35 U.S.C. §112, Second Paragraph

Claims 3-7 and 12 stand rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite. As claim 5 has been canceled, the rejection as applied to this claim is rendered moot.

Applicants have amended the claims, where appropriate, to recite "nucleic acid sequence." The term "sequence," which is what a sequence identifier denotes, is a term of art and would be known to one of skill in the biotechnology art, to which this invention belongs. As such, one of skill in the art would understand the metes and bounds of the claims.

For these reasons, Applicants respectfully request that the rejection be withdrawn.

Rejections Under 35 U.S.C. §102

Claims 1 and 2 stand rejected under 35 U.S.C. §102(b), as allegedly being anticipated by Bohne et al., Blais et al., or Camilli et al.

Applicants traverse the rejection as it might apply to the amended claims, including claims dependent therefrom, for the reasons given below.

The Office Action alleges, in pertinent part, that the cited references teach the elements as recited in the present claims, specifically, that the references teach virulence genes "*prfA*, *pclA*, *hyl*[sic], *mpl*, *plcB*, and *actA*." The instant claims have been amended to recite a specific sequence identifier: i.e., SEQ ID NO: 9. Review of SEQ ID NO: 9 demonstrates that a contiguous reading frame is present within residues 887 to 1500, which delimit a target for PCR amplification using primers defined by SEQ ID NO:26 and SEQ ID NO:27. As a point of reference, the predicted amino acid sequence for this contiguous reading frame is given below:

"VTPLTQLTYFDCSVNPLTELDVSTLSKLTTLHCIQTDLLEIDLTHNTQLIYFQAEGCRKI
KELDVTHNTQLYLLDCQAAGITELDLSQNPKLVYLYLNNTELTELDVSHNTKLKSLSCVN
AHIQDFSSVGKIPALNNNFEAEGQTITMPKETLTNNSLTIAVSPDLLDQFGNPMNIEPGD
GGVYDQATNTITWENLSTDNPAV"

Review of the amino acid sequences available from the National Center for Biotechnology Information (NCBI) for the sequences recited in the Action (see, e.g., Exhibits A-F), show that no significant homology exists between the virulence genes recited in the Action and the predicted amino acid sequence from the contiguous reading frame present within SEQ ID NO: 9. Because the present claims expressly recite a sequence identifier, which is not taught or suggested in the references cited, neither Bohne et al., Blais et al, nor Camilli et al., separately or in combination, anticipate the claimed invention.

As stated in Hybritech Inc. v. Monoclonal Antibody, Inc., 231 U.S.P.Q. 81 (Fed. Cir. 1986), "It is axiomatic that for prior art to anticipate under 102 it has to meet every element of the claimed invention."

Therefore, because the instant claims recite a sequence identifier which is not taught or suggested in the references cited, the cited references, alone or in combination, do not anticipate the claimed invention.

Failure of the prior art to meet every element of the claimed invention does not meet the standard under §102. For these reasons, Applicants respectfully request that the rejection be withdrawn.

Claims 1-14 stand rejected under 35 U.S.C. §102(b), as allegedly being anticipated by Kunst et al. or Glasner et al. As Claims 5 and 12 have been canceled, the rejection as applied the these claims is rendered moot.

Applicants traverse the rejection as it might apply to the amended claims, including claims dependent therefrom, for the reasons given below.

The Office Action alleges, in pertinent part, that the cited references teaches the elements as recited in the present claims. Glasner et al. is offered to demonstrate the isolation of virulence genes "*prfA*, *pclA*, *hyl*[sic], *mpl*, *plcB*, and *actA*." Again, as stated above, the instant claims have been amended to recite a specific sequence identifier: i.e., SEQ ID NO: 9. Review of SEQ ID NO:9 demonstrates that a contiguous reading frame is present within residues 887 to 1500, which delimit a target for PCR amplification using primers defined by SEQ ID NO:26 and SEQ ID NO:27. As a point of reference, the predicted amino acid sequence for this contiguous reading frame is given below:

"VTPLTQLTYFDCSVNPLTELDVSTLSKLTTLHCIQTDLLEIDLTHNTQLIYFQAEGCRKI
KELDVTHNTQLYLLDCQAAGITELDLSQNPKLVYLYLNNTELTELDVSHNTKLKSLSCVN

AHIQDFSSVGKIPALNNNFEAEGQTITMPKETLTNNSLTIAVSPDLLDQFGNPMNIEPGD
GGVYDQATNTITWENLSTDNPAV"

Review of the amino acid sequences available from NCBI for the sequences recited in the Action (see, e.g., Exhibits A-F), show that no significant homology exists between the virulence genes recited in the Action and the predicted amino acid sequence from the contiguous reading frame present within SEQ ID NO: 9. Because the present claims expressly recite the sequence identifier, which is not taught or suggested in Glaser et al., the reference does not anticipate the claimed invention.

Regarding Kunst et al., the Office Action states that the claimed sequences, SEQ ID NO: 9, 26, and 27, are disclosed in the reference. While it is not clear as to which search report the Action is referring to in support of the statement that the sequence identifiers are disclosed, the Kunst et al. sequences can be obtained from the PTO website at, for example: http://seqdata.uspto.gov/?pageRequest=viewSequecne&DocID=20040018514&seqID=2870 and http://seqdata.uspto.gov/?pageRequest=viewSequence&DocID=US20040018514A1&seqID=2909.

Applicants submit that review of SEQ ID NO: 2909 and 2870 demonstrates that these sequences do not anticipate SEQ ID NO: 9, 26, or 27 as claimed.

Exhibits G and H represent the nucleic acid sequences denoted by sequence identifiers 2870 and 2909 of Kunst et al. At minimum, because both SEQ ID NO: 2870 and 2909 have fewer nucleotides than SEQ ID NO: 9 (2556/759 vs. 2640), SEQ ID NO: 2870 and 2909 are not identical to SEQ ID NO: 9, and thus, do not anticipate SEQ ID NO: 9 as claimed.

Further, Applicants submit that there is no teaching in Kunst et al. which would lead one of skill in the art to make the primers as recited. In the same fashion that genomes do not

inherently anticipate isolated structural genes for want of enablement, Kunst et al. do not provide sufficient guidance to specifically identify the primer sequences as claimed (see, e.g., Chester v. Miller, 15 U.S.P.Q.2d 1281 (Fed. Cir. 1990), where the court stated that "[t]o be prior art under section 102(b), the reference must put the anticipating subject matter at issue into the possession of the public through an enabling disclosure."). Both SEQ ID NOS: 2870 (2556 nt) and 2909 (759 nt) are orders of magnitude longer that either SEQ ID NO: 26 (21 nt) or 27 (20 nt). And while Kunst et al. may or may not suggest the use of primers for the detection of *Listeria* contamination, there is no guidance which would direct the skilled artisan to choose the specific primers as claimed among all the possible alternative fragments that comprise SEQ ID NOS: 2870 and/or 2909.

As stated in Hybritech Inc. v. Monoclonal Antibody, Inc., 231 U.S.P.Q. 81 (Fed. Cir. 1986), "It is axiomatic that for prior art to anticipate under 102 it has to meet every element of the claimed invention."

Therefore, because the instant claims a) recite a sequence identifier which is not taught or suggested in the cited references and b) recite specific primer sequences which would not be enabled by the teachings of the cited references, neither Glasner et al. nor Kunst et al. anticipate the claimed invention.

Failure of the prior art to meet every element of the claimed invention does not meet the standard under §102. For these reasons, Applicants respectfully request that the rejection be withdrawn.

In light of the above, Applicants submit that this application is now in condition for allowance and therefore request favorable consideration. If any issues remain which the Examiner feels may be best resolved through a personal or telephonic interview, the Examiner is respectfully requested to contact Applicants counsel, James M. Heintz at 202.861.4167.

Respectfully submitted,

DLA PIPER US LLP

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Facsimile No. 202.223.2085

EXHIBIT A

☐ 1: CAA43524. Reports prfA [Listeria mo...[gi:48960]

Comment Features Sequence

```
LOCUS       CAA43524                 237 aa            linear   BCT 12-JUN-2006
DEFINITION  prfA [Listeria monocytogenes].
ACCESSION   CAA43524
VERSION     CAA43524.1  GI:48960
DBSOURCE    embl accession X61210.1
KEYWORDS    .
SOURCE      Listeria monocytogenes
  ORGANISM  Listeria monocytogenes
            Bacteria; Firmicutes; Bacillales; Listeriaceae; Listeria.
REFERENCE   1
  AUTHORS   Mengaud,J., Dramsi,S., Gouin,E., Vazquez-Boland,J.A., Milon,G. and
            Cossart,P.
  TITLE     Pleiotropic control of Listeria monocytogenes virulence factors by
            a gene that is autoregulated
  JOURNAL   Mol. Microbiol. 5 (9), 2273-2283 (1991)
   PUBMED   1662763
REFERENCE   2  (residues 1 to 237)
  AUTHORS   Dramsi,S., Kocks,C., Forestier,C. and Cossart,P.
  TITLE     Internalin-mediated invasion of epithelial cells by Listeria
            monocytogenes is regulated by the bacterial growth state,
            temperature and the pleiotropic activator prfA
  JOURNAL   Mol. Microbiol. 9 (5), 931-941 (1993)
   PUBMED   7934921
REFERENCE   3  (residues 1 to 237)
  AUTHORS   Cossart,P.F.
  TITLE     Direct Submission
  JOURNAL   Submitted (09-AUG-1991) P.F. Cossart, Inst Pasteur, Lab de Gen Mol
            des Listeria, 28 rue du DR. Roux, 75015 Paris, FRANCE
COMMENT     See M55160 for overlapping sequence.
FEATURES             Location/Qualifiers
     source          1..237
                     /organism="Listeria monocytogenes"
                     /strain="LO28"
                     /db_xref="taxon:1639"
     Protein         1..237
                     /name="prfA"
     Region          18..210
                     /region_name="Crp"
                     /note="cAMP-binding proteins - catabolite gene activator
                     and regulatory subunit of cAMP-dependent protein kinases
                     [Signal transduction mechanisms]; COG0664"
                     /db_xref="CDD:31008"
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     CDS             1..237
                     /gene="prfA"
                     /coded_by="X61210.1:274..987"
                     /transl_table=11
                     /db_xref="GOA:P22262"
                     /db_xref="InterPro:IPR000595"
                     /db_xref="InterPro:IPR001808"
                     /db_xref="InterPro:IPR011991"
                     /db_xref="InterPro:IPR012318"
                     /db_xref="PDB:1OMI"
                     /db_xref="PDB:2BEO"
                     /db_xref="PDB:2BGC"
                     /db_xref="UniProtKB/Swiss-Prot:P22262"
ORIGIN
        1 mnaqaeefkk yletngikpk qfhkkelifn qwdpqeycif lydgitklts isengtimnl
       61 qyykgafvim sgfidtetsv gyynlevise qatayvikin elkellsknl thffyvfqtl
      121 qkqvsyslak fndfsingkl gsicgqllil tyvygketpd gikitldnlt mqelgyssgi
      181 ahssavsrii sklkqekviv yknscfyvqn ldylkryapk ldewfylacp atwgkln
//
```

EXHIBIT B

1: AAY54619. Reports PlcA [Listeria mo...[gi:66737346]

Features Sequence

```
LOCUS       AAY54619                269 aa            linear   BCT 21-AUG-2006
DEFINITION  PlcA [Listeria monocytogenes].
ACCESSION   AAY54619
VERSION     AAY54619.1  GI:66737346
DBSOURCE    accession DQ054593.1
KEYWORDS    .
SOURCE      Listeria monocytogenes
  ORGANISM  Listeria monocytogenes
            Bacteria; Firmicutes; Bacillales; Listeriaceae; Listeria.
REFERENCE   1  (residues 1 to 269)
  AUTHORS   Jiang,L.L., Xu,J.J., Chen,N., Shuai,J.B. and Fang,W.H.
  TITLE     Virulence phenotyping and molecular characterization of a
            low-pathogenicity isolate of Listeria monocytogenes from cow's milk
  JOURNAL   Acta Biochim. Biophys. Sin. (Shanghai) 38 (4), 262-270 (2006)
   PUBMED   16604266
REFERENCE   2  (residues 1 to 269)
  AUTHORS   Jiang,L., Xu,J., Chen,N., Shuai,J. and Fang,W.
  TITLE     Direct Submission
  JOURNAL   Submitted (07-MAY-2005) Institute of Preventive Veterinary
            Medicine, College of Animal Science, 268 Kaixuan Road, Hangzhou,
            Zhejiang 310029, China
COMMENT     Method: conceptual translation.
FEATURES             Location/Qualifiers
     source          1..269
                     /organism="Listeria monocytogenes"
                     /strain="10403S"
                     /db_xref="taxon:1639"
     Protein         1..269
                     /product="PlcA"
     Region          1..256
                     /region_name="PLCc"
                     /note="Phospholipase C, catalytic domain;
                     Phosphoinositide-specific phospholipases C catalyze
                     hydrolysis of phosphatidylinositol-4,5-bisphosphate (PIP2)
                     to D-myo-inositol-1,4,5-trisphosphate (1,4,5-IP3) and
                     sn-1,2-diacylglycerol (DAG); cd00137"
                     /db_xref="CDD:58311"
     CDS             1..269
                     /gene="plcA"
                     /coded_by="DQ054593.1:1..810"
                     /transl_table=11
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     121 kdyfyttprt dtsnkiptlk dvrgkillls enhtkkplvi nsrkfgmqfg apnqviqddy
     181 ngpsvktkfk eivqtayqas kadnklflnh isatsltftp rqyaaalnnk veqfvlnlts
     241 ekvrglgili mdfpekqtik niiknnkfn
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EXHIBIT C

1: AAY54621. Reports Mpl [Listeria mon...[gi:66737350]

BLink, Conserved Domains, Links

Features Sequence

```
LOCUS       AAY54621                 510 aa            linear   BCT 21-AUG-2006
DEFINITION  Mpl [Listeria monocytogenes].
ACCESSION   AAY54621
VERSION     AAY54621.1  GI:66737350
DBSOURCE    accession DQ054595.1
KEYWORDS    .
SOURCE      Listeria monocytogenes
  ORGANISM  Listeria monocytogenes
            Bacteria; Firmicutes; Bacillales; Listeriaceae; Listeria.
REFERENCE   1  (residues 1 to 510)
  AUTHORS   Jiang,L.L., Xu,J.J., Chen,N., Shuai,J.B. and Fang,W.H.
  TITLE     Virulence phenotyping and molecular characterization of a
            low-pathogenicity isolate of Listeria monocytogenes from cow's milk
  JOURNAL   Acta Biochim. Biophys. Sin. (Shanghai) 38 (4), 262-270 (2006)
   PUBMED   16604266
REFERENCE   2  (residues 1 to 510)
  AUTHORS   Jiang,L., Xu,J., Chen,N., Shuai,J. and Fang,W.
  TITLE     Direct Submission
  JOURNAL   Submitted (07-MAY-2005) Institute of Preventive Veterinary
            Medicine, College of Animal Science, 268 Kaixuan Road, Hangzhou,
            Zhejiang 310029, China
COMMENT     Method: conceptual translation.
FEATURES             Location/Qualifiers
     source          1..510
                     /organism="Listeria monocytogenes"
                     /strain="10403S"
                     /db_xref="taxon:1639"
     Protein         1..510
                     /product="Mpl"
     Region          36..510
                     /region_name="LasB"
                     /note="Zinc metalloprotease (elastase) [Amino acid
                     transport and metabolism]; COG3227"
                     /db_xref="CDD:33040"
     Region          60..196
                     /region_name="Pep_M4_propep"
                     /note="Thermolysin metallopeptidase, propeptide;
                     pfam03413"
                     /db_xref="CDD:43339"
     Region          203..358
                     /region_name="Peptidase_M4"
                     /note="Thermolysin metallopeptidase, catalytic domain;
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                     pfam01447"
                     /db_xref="CDD:41495"
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                     pfam02868"
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                     /transl_table=11
ORIGIN
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       61 fkildmtkdk lgvthytlal ssggyltdnd eikvhvtpdn kitfingdlq qgqlritnqi
      121 kiteknaiek afeaigqsea hvksyvgnpv kekeiilnsr tkrlvynikl ifaepevasw
      181 ivqvdaetga ilkkqnmlse veradthkdf qalgkganrl lqrplhvmki ndlfylvdrt
      241 hkglirtfdl khntdtsfgk vvsnktnmft dpefssavda hfyasevyey yknvhqlesl
      301 dgkggeidsf vhyglncnna fwdgqeilyg dgdkknfkpf scaktivghe lthaviqysa
      361 gleyegqsga lnesfadvfg yfiapnhwli gedvcvrgsr dgrirsikdp dkynqaahmk
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EXHIBIT D

1: AAY54609. Reports PlcB [Listeria mo...[gi:66737326]

BLink, Conserved Domains, Links

Features Sequence

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LOCUS       AAY54609                289 aa            linear   BCT 21-AUG-2006
DEFINITION  PlcB [Listeria monocytogenes].
ACCESSION   AAY54609
VERSION     AAY54609.1  GI:66737326
DBSOURCE    accession DQ054583.1
KEYWORDS    .
SOURCE      Listeria monocytogenes
  ORGANISM  Listeria monocytogenes
            Bacteria; Firmicutes; Bacillales; Listeriaceae; Listeria.
REFERENCE   1  (residues 1 to 289)
  AUTHORS   Jiang,L.L., Xu,J.J., Chen,N., Shuai,J.B. and Fang,W.H.
  TITLE     Virulence phenotyping and molecular characterization of a
            low-pathogenicity isolate of Listeria monocytogenes from cow's milk
  JOURNAL   Acta Biochim. Biophys. Sin. (Shanghai) 38 (4), 262-270 (2006)
   PUBMED   16604266
REFERENCE   2  (residues 1 to 289)
  AUTHORS   Jiang,L., Xu,J., Chen,N., Shuai,J. and Fang,W.
  TITLE     Direct Submission
  JOURNAL   Submitted (07-MAY-2005) Institute of Preventive Veterinary
            Medicine, College of Animal Science, 268 Kaixuan Road, Hangzhou,
            Zhejiang 310029, China
COMMENT     Method: conceptual translation.
FEATURES             Location/Qualifiers
     source          1..289
                     /organism="Listeria monocytogenes"
                     /strain="10403S"
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     Protein         1..289
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     Region          1..289
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                     /note="Zinc dependent phospholipase C; pfam00882"
                     /db_xref="CDD:40959"
     CDS             1..289
                     /gene="plcB"
                     /coded_by="DQ054583.1:1..870"
                     /transl_table=11
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      121 fynpdrdnty lpgfanakit gakyfnqsvt dyregkfdta fyklglaihy ytdisqpmha
      181 nnftaisypp gyhcayenyv dtikhnyqat edmvakrfcs ddvkdwlyen akrakadypk
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Jan 29 2007 13:59:11

EXHIBIT E

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                     /db_xref="CDD:44961"
     Region          <368..604
                     /region_name="ActA"
                     /note="ActA Protein; pfam05058"
                     /db_xref="CDD:44961"
     CDS             1..604
                     /gene="actA"
                     /coded_by="DQ309937.1:9..1823"
                     /transl_table=11
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      181 vadasesdld ssmqsadest pqplkanqkp ffpkvfkkik dagkwvrdki denpevkkai
      241 vdksaglidq lltkkkseev nasdfppppt deelrlalpe tpmllgfnap tpsepssfef
      301 pppptedele imretapsld ssftsgdlas lrsainrhse nfsdfppipt eeelngrggr
      361 ptseefssmn sgdftddens etteaeidrl adlrdrgtgk hsrnagflpl npfisspvps
      421 ltpkvpkisa palisditkk apfknpsqpl nvfnkktttk tvtkkptpvk tapklaelpa
      481 tkpqetvlre nktpfiekqa etnkqsinmp slpviqkeat esdkeemkpq teekmveese
      541 sannangknr sagieegkli aksaedekak eepgnhttli lamlaigvfs lgafikiiql
      601 rknn
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EXHIBIT F

1: ABH11412. Reports HlyA [Listeria mo...[gi:115395038]

BLink, Conserved Domains, Links

Features Sequence

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LOCUS       ABH11412                277 aa            linear   BCT 27-DEC-2006
DEFINITION  HlyA [Listeria monocytogenes].
ACCESSION   ABH11412
VERSION     ABH11412.1  GI:115395038
DBSOURCE    accession DQ812517.1
KEYWORDS    .
SOURCE      Listeria monocytogenes
  ORGANISM  Listeria monocytogenes
            Bacteria; Firmicutes; Bacillales; Listeriaceae; Listeria.
REFERENCE   1  (residues 1 to 277)
  AUTHORS   Ducey,T.F., Page,B., Usgaard,T., Borucki,M.K., Pupedis,K. and
            Ward,T.J.
  TITLE     A Single-Nucleotide-Polymorphism-Based Multilocus Genotyping Assay
            for Subtyping Lineage I Isolates of Listeria monocytogenes
  JOURNAL   Appl. Environ. Microbiol. 73 (1), 133-147 (2007)
   PUBMED   17085705
REFERENCE   2  (residues 1 to 277)
  AUTHORS   Ducey,T.F., Page,B., Usgaard,T., Borucki,M.K., Pupedis,K. and
            Ward,T.J.
  TITLE     Direct Submission
  JOURNAL   Submitted (22-JUN-2006) Microbial Genomics and Bioprocessing
            Research Unit, United States Department of Agriculture,
            Agricultural Research Service, 1815 N. University Street, Peoria,
            IL 61604, USA
COMMENT     Method: conceptual translation.
FEATURES             Location/Qualifiers
     source          1..277
                     /organism="Listeria monocytogenes"
                     /strain="NRRL 33466"
                     /db_xref="taxon:1639"
     Protein         <1..>277
                     /product="HlyA"
     Region          <1..277
                     /region_name="Thiol_cytolysin"
                     /note="Thiol-activated cytolysin; pfam01289"
                     /db_xref="CDD:41345"
     CDS             1..277
                     /gene="hlyA"
                     /coded_by="DQ812517.1:<1..>831"
                     /transl_table=11
ORIGIN
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      241 sklahftssi ylpgnarnin vyakectgla wewwrtv
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EXHIBIT G

Publication Site for Issued and Published Sequences (PSIPS)

PSIPS View Sequence(s): 2870 for 20040018514

Here is the list of the requested sequences.

Sequence ID No: Go

First Sequence
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Help Page
FAQ

<210> SEQ ID NO 2870
<211> LENGTH: 2556
<212> TYPE: DNA
<213> ORGANISM: Listeria monocytogenes EGDe
<400> SEQUENCE: 2870

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aaagaaacaa gctcaactca accaactata aaaaacacac tcaaagccgg tcaaacacaa
agttttaacg actggtttcc tgatgacaat tttgcttcag aggtagcagc agcatttgaa
atgcaagcaa ctgacactat cagcgaagaa caactagcta ctctaacaag tctagattgc
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atttgcacaa gtaacaacat taccaccctt gatcttagcc aaaacactaa tttaacttat
ctggcatgtg attcaaataa acttacaaac cttgacgtaa ccccgcttac aaaattaacc
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EXHIBIT H

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